UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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JANSSEN PHARMACEUTICA N.V.,

Plaintiff,

- against -

EON LABS MANUFACTURING, INC.,

Defendant.

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REPORT & RECOMMENDATION

CV 01-2322 (NG) (MDG)

GO, United States Magistrate Judge:

Plaintiff Janssen Pharmaceutica, N.V. ("Janssen") brings this action for patent infringement pursuant to 35 U.S.C. § 271(e)(2) alleging that defendant Eon Labs Manufacturing Corporation, Inc. ("Eon") infringed on Janssen's patent for an anti-fungal medication, SPORANOX®. Eon has moved for summary judgment on plaintiff's claim of infringement on the ground that its proposed product cannot literally infringe Janssen's patent and that the prosecution history bars application of the doctrine of equivalents. The Honorable Nina Gershon referred this and all other pretrial motions to me for report and recommendation. On June 30, 2003, this court held a Markman hearing to hear testimony and oral argument on the parties' claim construction.

BACKGROUND

On May 27, 1997, the United States Patent and Trademark Office granted Janssen United States Letters Patent No. 5,633,015

("the '015 patent") entitled "Beads Having A Core Coated With An Antifungal And A Polymer." See Amended Complaint ("Am. Cmpl.") at ¶ 5. The '015 patent claims a drug delivery system that allows poorly soluble itraconazole molecules to be delivered to the patient in an oral dosage form and its use in treating fungal infections. See Plaintiff's Exh. ("Pl.'s Exh.") 2 (the '015 patent). The '015 patent was approved by the United States Patent and Trademark Office ("PTO") on March 13, 1995. Id. Plaintiff later filed a certificate of correction correcting typographic errors in the patent. See Transcript of June 30, 2003 Hearing ("Tr.") at 74; Defendant's Exh. ("Def.'s Exh.") 141. Plaintiff markets the commercial embodiment of the invention claimed under the '015 patent under the product name SPORANOX®. See Pl.'s Exh. 1 (Declaration of Roland Bodmeier ("Bodmeier Decl.")), Exh. 2.

In February, 2001, Eon filed an Abbreviated New Drug Application ("ANDA") pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act, seeking approval to manufacture, use and sell a generic version of SPORANOX®. See 21 U.S.C. § 355(j)(1994);[1] 21 C.F.R. § 314 Subpart C; Am. Cmpl. at ¶ 6;

[1] Section 355(j) sets forth procedures for a generic drug manufacturer to seek expedited approval from the Food and Drug Administration ("FDA") to market a generic version of an already-approved drug. See Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1570 (Fed. Cir. 1997). It also provides protection for a drug manufacturer owning an unexpired patent relevant to a proposed drug by suspending FDA approval of the ANDA pending judicial determination of whether the proposed drug infringes on the manufacturer's patent. See id.

Declaration of Sadie Ciganek in Support of Defendant's Motion ("Ciganek Decl."), Exhs. A, B. On or about February 26, 2001, Eon sent a letter to Janssen giving notice of the ANDA and containing the certification required by 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that its proposed itraconazole capsules did not infringe on the '015 patent. See Am. Cmpl. at ¶ 7; Ciganek Decl., Exh. E. Eon claimed that its proposed generic version of SPORANOX® differed from the '015 patent because the size of the sugar cores in the proposed generic version was larger than that claimed in the '015 patent. See Am. Cmpl. at ¶ 7; Ciganek Decl., Exh. E.

On April 13, 2001, Janssen filed this action against Eon alleging that the product described in Eon's ANDA would violate Janssen's '015 patent.[2] See Cmpl. On December 10, 2001, Janssen amended its complaint to add a claim for willful infringement. See Am. Cmpl. at ¶ 10. In its amended complaint, plaintiff seeks to bar Eon from manufacturing, using or selling its generic

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[2] Thirty-five U.S.C. § 271(e)(2)(A) provides that it shall be an act of infringement to submit an ANDA "if the purpose of such a submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." This "act of infringement" is said to be "artificial" because "a specific infringing composition has not yet been made, used, or sold and is thus not necessarily available for a court to compare to the claims." Glaxo, 110 F.3d at 1569. Therefore, in an action under § 271(e)(2), the focus is on "what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred." Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1248 (Fed. Cir. 2000) (en banc); Glaxo, 110 F.3d at 1569.

version of SPORANOX® until the expiration of the '015 patent and to enjoin FDA approval of Eon's generic version of SPORANOX® until the expiration of the '015 patent, as well as damages. Eon has asserted affirmative defenses and counter-claims that the '015 patent is invalid, unenforceable and not infringed by Eon's proposed product.

Prior to the completion of fact discovery, Eon filed the instant motion for summary judgment. This Court deferred determination of the motion pending more discovery and a Markman hearing.

The '015 Patent

The '015 patent concerns a new drug delivery system for certain antifungal agents such as itraconazole and saperconazole. See '015 patent (col. 1, lns. 12-13). Prior to the '015 patent, effective administration of these antifungals was difficult because of poor solubility in water and meager bioavailability. See id. (col. 1, lns. 16-23). The '015 patent proposes a composition consisting of spherical sugar cores coated with a mixture of itraconazole and a hydrophilic polymer and then sealed with a polymer layer, which improves bioavailability. See id. (col. 1, lns. 39-45). Besides proposing a novel composition, the '015 patent states that it also concerns a process for preparing the composition and the pharmaceutical dosage forms for oral administration of the composition. See id. (col. 1, lns. 11-15).

Claim 1 concerns the composition of the bead and is the only independent claim of the '015 patent. As the parties agree, all other claims depend on it. Claim 1 reads:

> 1. A bead comprising:
>
> a. a central, rounded or spherical core;
>
> b. a coating film of a hydrophilic polymer and an antifungal agent selected from the group consisting of itraconazole and saperconazole, and
>
> c. a seal-coating polymer layer, characterized in that the core has a diameter of from about 600 to about 700 um (25-30 mesh).

Id. (col. 6, lns. 17-24). According to the '015 patent, the size of the sugar cores used is critical to the manufacturing process: cores too small have a tendency to agglomerate and cores too large may require a more intensive drying step to reduce residual solvent levels that adversely affect drug dissolution. See id. (col. 1, ln. 58 to col. 2, ln. 8). In other words, use of sugar cores that are too big required over drying and use of sugar cores that are too small resulted in agglomeration - i.e., causing the cores to stick together. Tr. at 18-19. The only difference between Eon's proposed product and SPORANOX® is that Eon proposes a product based on a 30-35 mesh cut, which it contends falls outside the range "of from about 600 to about 700 um (25-30 mesh)" specified in claim 1 of the '015 patent. See Ciganek Decl., Exh. E at 8.

At the Markman hearing, plaintiff's expert, Professor Roland Bodmeier, testified that one with ordinary skill in the art of the '015 patent would interpret claim 1 as claiming one bead with a particle size of from approximately 600-700 um. Dr. Bodmeier contended that the parenthetical reference to mesh size signifies there is a high probability that a bead with that particle size would be found in 25-30 mesh. In contrast, Harry Brittain, defendant's expert, testified that one with ordinary skill in the art of the '015 patent would interpret claim 1 as claiming beads with 25-30 mesh cores that would have a minimum of 80% of particles in the 600-700 um range.

Other than their differences in opinion regarding the construction of claim 1, both experts agreed that the size of the sugar core in a bead described in claim 1 is necessarily approximate. Tr. at 24-25, 89. Although the diameter of a sugar core can be precisely measured through electron microscopy, pharmaceutical companies or other manufacturers working with sugar spheres expect a degree of tolerance in the size of the spheres used. Tr. at 25, 50, 55, 76-77. This is because sugar spheres, as well as other microparticles, are commonly separated by size through metallic filters referred to as "mesh" screens in the industry. Tr. at 25-26; 77-78.

The mesh size corresponds to the number of openings per linear inch. Tr. at 26-27. For example, a 20 mesh screen contains 20 circular openings per inch while a 25 mesh screen

defines a screen having 25 circular openings on the same inch of surface. Tr. at 26-27. The higher the mesh number, the larger number of openings on a given surface and, hence, the smaller the openings.

Due to the variability in the size of screen openings, the actual size of openings in a mesh screen varies within a given range of tolerances.[3] Tr. at 27-28. For example, the average size of openings on a 25 mesh screen actually ranges from 680 to 740 micrometers. Id. In order to obtain sugar spheres within the 25-30 mesh size range, the sugar spheres must be filtered through two screens stacked one on top of the other. Tr. at 35, 115. The sugar spheres that pass through the openings of the 25 mesh screen are then filtered through a 30 mesh screen. The spheres that remain on top of the 30 mesh screen but which passed through the openings of a 25 mesh screen are said to be within the specific size range 25-30 mesh. Id.

The United States Pharmacopeia ("USP"), in conjunction with the National Formulary, has established the accepted standards for sieving particles which are published in "USP NF Official Compendium of Standards" ("National Formulary standard"). Tr. at 39, 72; Pl.'s Exhs. 4, 7. The National Formulary standard requires that sieves used for screening conform to the standards

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[3] Dr. Bodmeier testified that the percentage of cores not within the 600-700 micrometer range would be 10% while Dr. Brittain testified that a typical tolerance would be 5%. Tr. at 25, 93.

of the American Society for Testing and Materials ("ASTM"). Pl.'s Exh. 4 at 2044. The ASTM sets the standard or nominal opening of a 25 mesh sieve at 710 micrometers and the 30 mesh sieve at 600 micrometers. Tr. at 28, 79; Pl.'s Exh. 5. Since the ASTM provides that dimensions of sieve openings not exceed 5% of the nominal opening, the upper limit for 25 mesh screens is 740 micrometers and the lower limit for 30 mesh screens is 575 micrometers. Id. Sugar cores or other particles of a 25 - 30 mesh cut are obtained by sieving them through a 25 mesh screen and the particles falling through are then sieved through a 30 mesh screen. Tr. at 35-56. According to National Formulary standards, the "particle size" with respect to sugar spheres (citing section 786) means that "not less than 90% of it passes the coarser sieve size stated in the labeling; all of it passes the next coarser sieve size . . . Not more than 10% passes the finer sieve size stated in the labeling." See Pl.'s Exh. 4. At least 80% of the particles remaining on the 30 mesh screen must be between the mesh cut of 600-710 micrometers. Tr. at 40, 88-89. Thus, 10% of the particles remaining on the 25 mesh screen and 10% of the particles falling through the 30 mesh screen may also be within the 600-710 micrometer ranges. Tr. at 88. Given the variation in screen size openings and the nature of the sieving process used to obtain particles of a particular mesh cut, it is impossible to obtain a manufacturing quantity of 25-30 mesh sugar spheres of pharmaceutical grade where every sphere

would fall within the 600-710 micrometers range for that mesh cut. Tr. at 49-50, 87-88, 91-93.

DISCUSSION

Courts frequently address claim construction and summary judgment in a single decision because the interpretation of a patent claim often has a great impact on whether there is infringement. See, e.g., Intellectual Property Development, Inc. v. UA-Columbia Cablevision of Westchester, 336 F.3d 1308 (Fed. Cir. 2003); Tehrani v. Hamilton Medical, Inc., 331 F.3d 1355 (Fed. Cir. 2003). Accordingly, the starting point in an infringement analysis is claim construction. Markman v. Westview Inst., Inc., 52 F.3d 967, 976 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996). In determining claim construction, the court first considers intrinsic evidence which consists of the claims, specification and prosecution history. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). The court should look at the language of the claim itself, which sets forth the scope of the claimed invention unless the written description requires a contrary reading. See Northern Telecom Ltd. v. Samsung Elecs., 215 F.3d 1281, 1287 (Fed. Cir. 2000); see also Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1324 (Fed. Cir. 2003) ("Claims are best understood in light of the specification of which they are a part").

The Federal Circuit has emphasized that it indulges a "heavy presumption" that a claim term carries its ordinary and customary

meaning, which may be determined by reviewing a variety of sources, including the claims themselves, other intrinsic evidence such as the written description and the prosecution history, as well as dictionaries and treatises. Teleflex Inc., v. Ficosa North America Corp., 299 F.3d 1313, 1324 (Fed. Cir. 2002); Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202 (Fed. Cir. 2002) ("dictionaries, encyclopedias and treatises are particularly useful resources to assist the court in determining the ordinary and customary meanings of claim terms"); Vitronics, 90 F.3d at 1582 (intrinsic evidence consists of claims, specification and prosecution history). The ordinary meaning of a claim or specification must be determined "as one of skill in the art at the time of the invention would understand them." Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F.3d 1547, 1555 (Fed. Cir. 1997), abrogated on other grounds by Cybor Corp. v. FAS Technologies, Inc., 336 F.3d 1308 (Fed. Cir. 1998); see also Teleflex, 299 F.3d at 1324.

"The use of extrinsic evidence to construe the scope of a claim is improper where the ordinary and accustomed meaning of a claim term does not render the claim unclear and where the patentee has not chosen to be his own lexicographer." Northern Telecom., 215 F.3d at 1288; see Vitronics, 90 F.3d at 1583-85 (court may look to extrinsic evidence only if intrinsic evidence is ambiguous). Extrinsic evidence, such as expert testimony, may be used where the intrinsic evidence cannot resolve ambiguities

in the claim language. While the Court may rely on expert testimony to understand the technology and the ordinary meaning of terms to practitioners of the art, expert testimony may not be used to contradict claim language or the specification. See Vitronics, 90 F.3d at 1583-84. The court may, in its discretion, consider extrinsic evidence for background and education, but it may not use such evidence to contradict the terms in the claims. Key Pharms. v. Hercon Labs. Corp., 161 F.3d 709, 716 (Fed. Cir. 1998) (citing Markman, 52 F.3d at 980-81).

The parties agree that the only issue of claim construction is the interpretation of the following part of claim 1: "A bead comprising: . . . [a coated central core] characterized in that the core has a diameter of from about 600 to about 700 um (25-30 mesh)." Specifically, Janssen argues that claim 1 refers to a single bead with a core of approximately 600-700 um and there is a high probability that a bead with that particle size would be found in the range of 25-30 mesh. In contrast, Eon urges that claim 1 be construed to refer to a plurality of beads with cores in the specific size range of 25-30 mesh of which at least 80% are from about 600-700 um. This distinction is critical to determination of infringement here because the only difference between Eon's proposed product and the '015 patent is that Eon proposes a core of 30-35 mesh rather than the range specified in claim 1 of the '015 patent.

Single Bead v. Plurality of Beads

Plaintiff argues that the phrase "a bead" in claim 1's preamble should be construed to limit the claim to a single bead. Plaintiff's Memorandum in Opposition ("Pl. Opp.") at 17-18. However, "much ink has, of course, been consumed in debates regarding when and to what extent claim preambles limit the scope of claims in which they appear." Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620 (Fed. Cir. 1995). "Whether to treat a preamble as a claim limitation is determined on the facts of each case in light of the claim as a whole and the invention described in the patent." Storage Technology Corp. v. Cisco Sys., Inc., 329 F.3d 823, 831 (Fed. Cir. 2003); see Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002). "If the preamble adds no limitations to those in the body of the claim, the preamble is not itself a claim limitation and is irrelevant to proper construction of the claim." IMS Technology, Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1434 (Fed. Cir. 2000); see In re Paulsen, 30 F.3d 1475, 1479 (Fed. Cir. 1994) ("[T]erms appearing in a preamble may be deemed limitations of a claim when they give meaning to the claims and properly define the invention"). Here, the term "bead" in the preamble of claim 1 describes the form of the novel composition, serving as a convenient label for the invention as a whole rather than as a limitation. See Storage Technology, 329 F.3d at 831 ("preamble terms 'policy caching

method' or 'policy cache' do not limit claim scope and simply refer to the invention set forth in the body of the claim"). Clearly, the subject matter of the invention, as the specification makes clear, is the oral administration of itraconazole, not "a bead."

Significantly, the term "bead" only appears in the claim 1 preamble and not the body of the claim. See Bell Communications, 55 F.3d at 621 (explicit incorporation of preamble found dispositive). Plaintiff describes the importance of the invention as follows: "By starting with rounded or spherical cores made of sugar or some other inactive ingredient, coating them with a mixture of the antifungal agent and a hydrophilic polymer, and then applying a seal-coating polymer layer, the inventors developed a structure that unexpectedly yielded good bioavailability for itraconazole." Pl. Opp. at 6. The description of the structure of the invention is contained in the body of the claim and is all that is required to give the claim its meaning. In re Paulsen, 30 F.3d at 1479-80 (examining whether preamble "breathes life and meaning into the claims"). Therefore, the preamble's reference to "a bead" is not a meaningful limitation on claim 1.

Even if the preamble acts as a limitation, plaintiff is wrong in arguing that the ordinary and customary meaning of the term "a bead" would be a bead in the singular. Pl. Opp. at 17-18. As the Federal Circuit has consistently recognized, the

words "'a' or 'an' can mean 'one' or 'more than one,' depending on the context in which the article is used." Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 978 (Fed. Cir. 1999). However, "the article 'a' receives a singular interpretation only in rare circumstances when the patentee evinces a clear intent to so limit the article." KCJ Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1356 (Fed. Cir. 2000). In patent parlance, particularly where, as here, the claim uses the open term "comprising," the indefinite article "a" or "an" means "one or more." See Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, 246 F.3d 1336, 1347 (Fed. Cir. 2001) (claim limitation "a" along with transitional phrase "comprising," "requires at least one"). Courts examining the context in which "a" or "an" is used have frequently found that term to mean more than one. See, e.g., Elkay Mfg., 192 F.3d at 977 ("'an upstanding feed tube' . . . is not necessarily limited to a single feed tube with a single flow path"); Altiris, Inc. v. Symantec Corp., 318 F.3d 1363, 1373-74 (Fed. Cir. 2003) ("'a boot selection flag' encompasses the use of multiple flags"); Tate Access Floors, Inc. v. Interface Architectural Resources, 279 F.3d 1357, 1370-71 (Fed. Cir. 2002) ("'an inner layer'" includes multiple layers); Construction Technology Inc. v. Lockformer Co., 713 F. Supp. 100, 105-06 (S.D.N.Y. 1989) (phrase "a third dimensional product" in preamble not interpreted in the singular); contrast RF Deleware, Inc. v. Pacific Keystone

Technologies, Inc., 326 F.3d 1255, 1265-66 (Fed. Cir. 2003) (looking at context of patent, court construed claim terms "filter bed" and "filter layer" in the singular where patent referred to "first particulate media with a filter layer"). Had the patent drafter intended to limit unequivocally the claim to a single bead, he could have written "a single bead." Since no other part of claim 1 evinces the intent to use the term "a bead" as a limitation, the court must look beyond the language of the preamble to ascertain the plain meaning of the term.

Among the intrinsic evidence, the specification "is the single best guide to the meaning of a disputed term." Teleflex, 299 F.3d at 1325 (citations omitted); see KCJ, 223 F.3d at 1356 ("[W]hen the claim language or context calls for further inquiry, this court consults the written description for a clear intent to limit the invention to a singular embodiment"); Abtox, Inc. v. Exitron Corp., 122 F.3d 1019, 1024 (Fed. Cir. 1997) (court determines meaning of claim terms by examining written description for fuller context). In fact, construing a claim in isolation without reading the claim in view of the specification of which it is a part would be "legal error." Bell Communications, 55 F.3d at 621. Thus, claim 1 must be read against the background of the specification. Solomon v. Kimberly-Clark Corp., 216 F.3d 1372, 1378 (Fed. Cir. 2000).

Unlike the claim 1 preamble, the specification repeatedly and almost exclusively uses the term "beads" rather than "a

bead." Most significantly, the specification includes a paragraph identical to claim 1 in all respects except that it refers to "beads which comprise . . ." See '015 patent (col. 1, lns. 46-47) (emphasis added). Moreover, the paragraph immediately preceding and following that section of the specification also uses the plural "beads." Elsewhere, in the discussion of the composition of the antifungals, the specification refers to "beads according to the present invention" three times. See '015 patent (col. 2, lns. 57, 63; col. 3, ln. 6) (emphasis added). The abstract also states that the "invention is concerned with beads comprising a 25-30 mesh core." See Hill-Rom Co. v. Kinetic Concepts, Inc., 209 F.3d 1337, 1341 n.* (Fed. Cir. 2000) (the abstract is a "helpful source of intrinsic evidence as to the meaning of claims").

In contrast, the singular form of the term "bead" only appears twice in the specification, both times, in the phrase "bead circulation," see column 3, lines 47, 49. There, the term "bead" is used as an adjective and, in context, clearly refers to the circulation of multiple beads.

Finally, the Patent Act requires that the specification of a patent "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112. The '015

patent does not teach how to make an individual bead with a specific micrometer size range. See PIN/NIP v. Platte Chemical Co., 304 F.3d 1235, 1244 (Fed. Cir. 2002) (term "composition" means mixture of two chemicals because specification "teaches only the mixture of the two ingredients"); Wang Laboratories, Inc. v. America Online, Inc., 197 F.3d 1377, 1382 (Fed. Cir. 1999) (construing claim to mean "character based system" because that is the "only system that is described and enabled" in the patent specification); Carroll Touch, Inc. v. Electro Mechanical Sys., Inc., 15 F.3d 1573, 1578 (Fed. Cir. 1993) (relying on specification's failure to teach proposed construction). Rather, the '015 patent speaks to the application of a mixture of antifungal agents and hydrophilic polymers "over many small beads, [to] yield[] a composition with good bioavailability which can be conveniently manufactured." See '015 patent (col. 1, lns. 40-44). Specifically, the manufacturing process described in the specification involves a drug coating process and a seal coating process yielding drug coated cores which are then dried. See '015 patent (col. 3, ln. 6 to col. 4, ln. 44). The process described in the specification would not produce an individual bead having a micrometer range of "about 600 to about 700 um," but, rather a plurality of beads.

Thus, I recommend that the Court construe the phrase "a bead" to mean more than one bead.

25-30 mesh v. about 600-700 um

The parties emphasize different portions of claim 1 to construe the phrase "the core has a diameter of from about 600 to about 700 um (25-30 mesh)." Plaintiff points to the micrometer range as the specific size range of the cores while defendant highlights the mesh size as the pertinent measure.

Under general principles of construction, a parenthetical is treated as the definition of the term which it follows. See Novacor Chemicals, Inc. v. United States, 171 F.3d 1376, 1381 (Fed. Cir. 1999); see also Johnson Worldwide Assoc., Inc. v. Zebco Corp., 50 F. Supp.2d 863 (W.D. Wisc. 1998) ("the specification . . . removes any doubt by parenthetically defining trolling motor to be the thrust motor"). Thus, I find the phrase "25-30 mesh" in parentheticals in claim 1 defines the "from about 600 to about 700 um" range. This interpretation is supported by the specification, which repeatedly uses the phrase "25-30 mesh" alone when referring to the size of the sugar cores. See, e.g., '015 patent (col. 2, lns. 6, 12, 27; col. 3, ln. 22). In contrast, the phrase "from about 600 to about 700 um" appears only twice and each time, only adjacent to the phrase "25-30 mesh." See id. (col. 1, lns. 51-52; col. 5, ln. 18). Additionally, both the abstract and dependent claim 3 use the phrase "25-30 mesh" to refer to the size of the claim 1 core without the micrometer range. See Hill-Rom, 209 F.3d at 1341 & n.* (relying on abstract). While mesh size is used

independently, the micrometer size is always qualified by the mesh size and dependent on the mesh size for its meaning.

Moreover, the "specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication," and is "the single best guide to the meaning of a disputed term." Vitronics, 90 F.3d at 1582; Ethicon Endo-Surgery, Inc. v. United States Surgical Corp., 93 F.3d 1572, 1578 (Fed. Cir. 1996). Here, the specification states "[a] particularly preferred material suitable for use as [cores] in the beads according to the present invention is represented by 25-30 mesh sugar spheres (NF XVII p 1989) . . ." See '015 patent (col. 2, lns. 25-30). This part of the specification plainly acts as a dictionary in defining the size of the cores in the invention in terms of mesh size according to the National Formulary. As plaintiff's expert, Dr. Bodmeier acknowledged, the National Formulary is recognized as the industry standard for setting the range of sugar sphere sizes. Tr. at 146 (mesh cut description is controlling definer of size of cores). This is also the standard accepted and applied by the U.S. Food and Drug Administration. See 21 U.S.C. §§ 321(j) (defining "official compendium" as the U.S. Pharmacopoeia/National Formulary), 351(b) ("determination as to strength, quality or purity shall be made in accordance with the tests or methods of assay set forth in" the official compendium); Tr. at 73. By referencing the National Formulary standard for determining the specific size range of the

sugar cores, the '015 patent has defined the size range as 25-30 mesh as measured by the National Formulary standards and within the tolerance level for variation in the National Formulary standards. Plaintiff's argument that construction of the disputed term to mean cores of a 25-30 mesh cut would eliminate the phrase "600 to 700 um" from claim 1 overlooks the significance of the "25-30 mesh" parenthetical to the preceding term.

In order to discern the usage of claim language amongst those of ordinary skill in the relevant art at the time of an invention, courts must consider a term's "meaning in the relevant community at the relevant time." ResQNet.com, Inc. v. Lansa, Inc., 346 F.3d 1374, 1378 (Fed. Cir. 2003). What is commonly known in the industry is relevant to how one of ordinary skill in the art would construe a term. Aktiengesellschaft v. Courtaulds Fibers, Inc., 119 F.3d 16 (Table), 44 U.S.P.Q.2d 1832 (Fed. Cir. July 14, 1997) ("standard operating procedure in the industry" is relevant to what one of ordinary skill in the art would conclude from reading terms); Novo Nordisk A/S v. Becton Dickinson and Co., 96 F. Supp.2d 309, 316 (S.D.N.Y. 2000) ("common industry knowledge" as to supplier of insulin needles raises issue of material fact as to understanding of one of ordinary skill in the art); cf. Smithkline Beecham Corp. v. Apotex Corp., 247 F. Supp.2d 1011, 1029-30 (N.D. Ill. 2003) (one of ordinary skill in the art "would not think the claim extended to the involuntary

creation of the crystalline form in quantities so minute as to be of no therapeutic, manufacturing, or other commercial significance").

Both expert witnesses testified that no manufacturer is able to supply sugar cores that are 100% within a given mesh size. Tr. at 49, 78-79, 87-88, 91-93; Def.'s Exh. 103. Dr. Brittain further testified that manufacturers of sugar spheres identify the spheres in terms of their mesh size rather than micrometers. See Tr. at 78-79, 91-93; Def.'s Exh. 103. Similarly, Dr. Bodmeier acknowledged that pharmaceutical companies are satisfied with the variation in sugar core sizes reflected in a specified mesh cut. Tr. at 50.

A person skilled in the art[4] would take into account the industry standard for the manufacture of sugar cores and other particles in construing the claims in the '015 patent. Cf. In re Alton, 76 F.3d 1168, 1175 (Fed. Cir. 1996) ("expert testimony about known industry standards in the 'art of extrusion ...'"

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[4] Defendant claims that the skilled artisan required in this case is essentially a technician with "experience in determining the particular size distribution of a granular solid using analytical sieving, and the procedures for report ..." Declaration of Harry G. Brittain in Support of Defendant's Motion ¶ 14. However, the '015 patent concerns a composition of which the central core is but one component, as well as a manufacturing process and pharmaceutical dosage forms. While knowledge of sieving techniques is relevant to the issue of core size, a skilled artisan here must have a background in pharmaceutics, chemistry, chemical engineering or a related field, with experience in the area of development of solid oral dosage forms. Bodmeier Decl. ¶ 47.

found to "expand the breadth of the actual written description"); Carnegie Mellon University v. Hoffman-La Roche, Inc., 148 F. Supp.2d 1004, 1011 (N.D. Cal. 2001). The knowledge available to a skilled artisan here includes the recognition that there is no way to insure that every sphere of pharmaceutical grade sugar will fall within a defined size range that is within the outer limits of a specified mesh cut (e.g., 600-710 um for a 25-30 mesh cut) and that the pharmaceutical grade sugar cores used for manufacturing will vary from the specified range within the distribution allowed by the National Formulary standards (i.e., particles ranging from 545-770 um, with at least 80% falling in the range of 600-710 um).

This Court is mindful that references to a preferred embodiment in a specification are not claim limitations. SRI Int'l. v. Matsushita Elec. Corp., 775 F.2d 1107, 1121 (Fed. Cir. 1985) (en banc); see also Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1187 (Fed. Cir. 1998) ("there is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification"). The specification states that "[m]aterials suitable for uses as cores in the bead are manifold, provided that said materials are pharmaceutically acceptable and have approximate dimensions (about 25-30 mesh) and firmness" (col. 2, lns. 9-13) (emphasis added). Besides identifying saccharides as "[p]articularly suitable materials" (col. 2, lns. 18-20), the

specification further identifies "25-30 mesh sugar spheres (NF XVIL p. 1989)" as "[a] particularly preferred material" (col. 2, lns. 25-28). Reading claim 1 in light of the specification and in light of industry standards for the stated materials, as recognized by a person skilled in the art, the reference to the National Formulary standards gives meaning to the parenthetical term "25-30 mesh" and defines the outer limit of the approximation reflected in the claim language "diameter of from about 600 to about 700 um."

For the foregoing reasons, I construe the disputed portion of claim 1 to mean beads with 25-30 mesh cores that would have cores in the 600-700 um range, in accordance with the variance permitted by National Formulary standards.

Prosecution History Estoppel

Eon argues on the basis of the prosecution history of the '015 patent that Janssen disclaimed any size range other than 600-700 um in its response to the patent examiner and therefore is estopped from claiming more than that specific size range. See Brief in Support of Defendant's Motion for Summary Judgment ("Def. Mot.") at 12-13. Defendant also argues prosecution history estoppel bars application of the doctrine of equivalents. Id. at 9-10.

"Even where the ordinary meaning of the claim is clear, it is well-established that the prosecution history limits the interpretation of claim terms so as to exclude any interpretation

that was disclaimed during prosecution." Pall Corp. v. PTI Techs., Inc., 259 F.3d 1383, 1392 (Fed. Cir. 2001) (citation and quotation marks omitted). This policy prevents patent applicants from construing claims more narrowly in order to obtain their allowance and then more broadly against accused infringers. See Spectrum Int'l, Inc. v. Sterilite Corp., 164 F.3d 1372, 1378 (Fed. Cir. 1998). "Explicit arguments made during prosecution to overcome prior art can lead to narrow claim interpretations because the public has a right to rely on such definitive statements made during prosecution." Rheox, Inc. v. Entact, Inc., 276 F.3d 1319, 1325 (Fed. Cir. 2002). The relevant question is whether the patent applicant made definitive statements or amendments that disclaimed or disavowed any subject matter. See Rheox, 276 F.3d at 1325.

The PTO initially rejected plaintiff's application "as being unpatentable over Dansereau in view of Fuisz." Pl.'s Exh. 6 (prosecution history) at A-00063. The Dansereau patent, No. 5,049,374, taught the oral administration of sodium iodide, a radioactive, highly water soluble substance, in a bead dosage form. See Declaration of Michael W. Krenicky in Support of Defendant's Motion ("Krenicky Decl."), Exh. C. The purpose of that patent was to minimize the radiation hazard of handling sodium iodide and to provide dosing flexibility for the drug. In contrast, the '015 patent is concerned with an oral dosage form designed to improve the bioavailability of antifungal agents,

including itraconazole that are poorly water soluble. Charles Metz, the prosecuting attorney, argued that because the problems faced by the inventors of the '015 patent were not addressed by the Dansereau patent, the '015 patent invention was not suggested by Dansereau. See id., Exh. B at A-00070-71. In particular, providing a practical oral dosage form for a poorly soluble drug was not addressed by Dansereau nor was the balance between avoiding an intensive drying step and avoiding agglomeration. See id. at A-00071.

In prosecuting the patent, Metz merely distinguished the '015 patent from the prior art on those grounds. Although he acknowledges that the preferred size of the core beads in the application is encompassed in the preferred size of the beads in the Dansereau patent, id., Metz's statement does not constitute disclaimer of any sugar core size range in order to obtain the patent. See IMS Technology, Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1438-39 (Fed. Cir. 2000) (patentee must clearly disavow claim coverage); York Prods. V. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1575 (Fed. Cir. 1996). Moreover, although not dispositive on prosecution history estoppel, no amendment to the core size limitation was made. York, 99 F.3d at 1575 ("Unless altering claim language to escape an examiner rejection, a patent applicant only limits claims during prosecution by clearly disavowing claim coverage"). Thus, I find that Janssen has not disclaimed any subject matter at issue here.

since Eon has failed to show that the amendment would give rise to estoppel, it has failed to meet its burden that Janssen "surrendered the particular equivalent in question." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 740, 122 S.Ct. 1831 (2002).

Literal Infringement

The second step of the infringement inquiry involves a determination "as to whether the properly construed claims read on the accused device." Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1304 (Fed. Cir. 1999). In the patent context, "summary judgment of non-infringement can only be granted if, after viewing the alleged facts in the light most favorable to the non-movant, there is no genuine issue whether the accused device is encompassed by the claims." Id.

Having construed claim 1 of the '015 patent to describe the sugar cores in terms of mesh size in accordance with the National Formulary standard, I find that Eon's ANDA, which defines its proposed product as being comprised of sugar cores of a different mesh size from the '015 patent, does not literally infringe. Both the '015 patent and Eon's ANDA describe sugar spheres in terms of the same National Formulary standard. Because the size range for each product is different in terms of the same objective standard, claim 1 of the '015 does not encompass Eon's proposed product. Moreover, the National Formulary prescribes a corresponding micron range for each mesh size so that Eon's

proposed product necessarily requires a micron size range outside the micron size range of the '015 patent by virtue of the different mesh size designation. In fact, because the mesh size defines the micron range, if there is no overlap between the mesh sizes, the micron size range must also be different.

The '015 patent's reliance on National Formulary standards by definition incorporates the accepted tolerance for variation among the size of sugar spheres. Accepting that tolerance, it is likely that each parties' mesh cut will contain a small percentage of sugar cores that could be found in the other party's mesh cut. Tr. at 119. However, any overlap is a byproduct of the imperfect process of analytical sieving. Janssen incorporated this size variation in the '015 patent by adopting the National Formulary standard. The references to mesh sizes in accordance with the National Formulary standards accepts a tolerance within which sugar core sizes may overlap in terms of microns and each still qualify as a particular mesh size. Using the standard adopted in the '015 patent for both parties' products distinguishes them from each other in terms of mesh size range regardless of any overlap in microns. Applying the National Formulary standard, at least 80% of Janssens' sugar cores pass through a 25 mesh screen but not a 30 mesh screen. In contrast, at least 80% of Eon's sugar cores would not pass through a 25 mesh screen. Eon's proposed product does not literally infringe because its specific sugar core size range is,

by definition, outside of the specific size range of claim 1 of the '015 patent.

Therefore, ANDA's proposed product does not literally infringe the '015 patent. However, the question of whether Eon infringes the '015 patent under the doctrine of equivalents remains, since the prosecution history does not bear a finding of equivalence. See Festo, 535 U.S. at 740.

CONCLUSION

For the foregoing reasons, I recommend that the Court construe claim 1 as set forth above. I further recommend that the Court grant defendant's motion for summary judgment, in part, on the question of literal noninfringement and deny the motion, in part, on the question of the doctrine of equivalents.

Copies of this report and recommendation have been sent by telecopier to the parties. Objections to the Report and Recommendation must be filed with the Clerk of Court, with a copy to the undersigned, by December 8, 2003. Failure to file objections within the time specified waives the right to appeal. See 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b).

SO ORDERED.

Dated: Brooklyn, New York
November 21, 2003

MARILYN
UNITED S

GE